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Cyclic pneumatic soft-tissue compression enhances recovery following fracture of the distal radius: a randomised controlled trial

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Questions: Does the addition of cyclic pneumatic soft-tissue compression during the 6-week immobilisation period following fracture of the distal radius result in a faster recovery of muscle strength and joint range of motion? Does it result in a larger recovery of muscle strength and joint range of motion immediately after the immobilisation period (at 6 weeks) or four weeks after the immobilisation period (at 10 weeks)? **Design:** Randomised controlled trial with concealed allocation and assessor blinding. **Participants:** 21 patients with fracture of the distal radius. **Intervention**: The experimental group received cyclic pneumatic soft-tissue compression during the 6-week immobilisation period whereas the control group received usual care. Both groups were instructed to actively make a fist 100 times per day during the 6-week immobilisation period and were given an exercise program during the 4-week post-immobilisation period. **Outcome measures**: Function was measured as power grip, pinch grip, key grip, and supination strength using dynamometry from Week 1 to 10 as well as wrist flexion/extension and forearm supination/pronation range of motion using goniometry from Week 6 to 10. The outcome measures are presented as a percentage of the intact side. **Results:** The experimental group improved significantly faster than the control group in muscle strength from Week 1 to 10 ($p \leq 0.001$) but not in joint range of motion from Week 6 to 10 ($p > 0.05$). By Week 6, the experimental group was 12–26% stronger and had 8–14% more range of motion than the control group. By Week 10, the experimental group was 24–29% stronger and had 10–15% more range of motion than the control group. **Conclusion:** The findings indicate that a larger clinical trial is warranted and should incorporate direct measures of fracture healing. **[Challis MJ, Jull GJ, Stanton WR, Welsh MK (2007) Cyclic pneumatic soft-tissue compression enhances recovery following fracture of the distal radius: a randomised controlled trial. *Australian Journal of Physiotherapy* 53: 247–252]**

Key words: Fracture Healing, Cyclic Compression, Fracture Compression, Pneumatic Pump, Randomized Controlled Trial

Introduction

It is well established both clinically and experimentally that fracture healing is largely dependent on the prevailing mechanical environment of the fracture (Sarmiento et al 1977, McKibbin 1978, Goodship and Kenwright 1985, Kenwright et al 1991, Kershaw et al 1993, Park et al 1998). Studies tend to suggest that there is an optimal mechanical environment for the progression of fracture healing, and that too much or too little of the wrong mechanical loading can hinder the process. Compressive forces probably constitute the greatest single positive influence on the mechanical environment of a healing fracture (Goodship and Kenwright 1985). Studies using both animal and human models have shown that intermittent compression or dynamic loading of long bone fractures enhances the rate of healing of these fractures and may promote the earlier return of normal function (Kenwright et al 1991, Goodship 1998, Hente et al 2004).

We have previously shown that the application of pneumatic soft-tissue compression applied to the musculature proximal to a fracture of the distal radius is able to create compressive forces at the fracture site (Challis et al 2005). Further, we found a beneficial effect when applying cyclic pneumatic soft-tissue compression to healing fractures of the distal radius in an *in vivo* ovine model (Challis et al 2006). In that study, the area of periosteal callus on X-ray, peak torsional strength, fracture stiffness, energy absorbed over the first ten degrees of torsion, and histomorphometric analysis were used to assess the progress of fracture healing. At four weeks, fractures treated with the cyclic pneumatic pressure were equivalent to control fractures at six weeks indicating a significant acceleration in fracture healing.

This preliminary study was conducted to investigate the effect of cyclic pneumatic soft-tissue compression, self-administered by use of a simple pneumatic compression apparatus, on the recovery of function following fracture of the distal radius. The research questions were:

1. Does the addition of cyclic pneumatic soft-tissue compression during the 6-week immobilisation period following fracture of the distal radius result in a faster recovery of muscle strength and joint range of motion?
2. Does it result in a larger recovery of muscle strength and joint range of motion immediately after the immobilisation period (at 6 weeks) or four weeks after the immobilisation period (at 10 weeks)?

Method

Design

A prospective, randomised controlled trial was carried out. Participants were volunteers from consecutive patients attending the fracture clinic of a general hospital in a regional area of Queensland, Australia. Patients were managed

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in a split forearm plaster immediately following fracture and prior to being recruited into the trial. Approximately one week post fracture, patients presented to the fracture clinic of the hospital where potential participants were identified by the fracture clinic nurse and recruited by one of the investigators (MC). The split cast was replaced with a full forearm plaster. All participants had an inflatable cuff positioned around their forearm under their plaster with the valve of the cuff protruding through the cast so that the independent assessor remained blind to group allocation during all measurements. Participants were then randomly allocated to either the experimental group or the control group by the fracture clinic nurse, who drew opaque envelopes containing the concealed group allocation from a box. All participants remained in plaster for a total of six weeks. The intervention was delivered for the last five weeks of the 6-week period of immobilisation. There was also a 4-week, post-immobilisation, follow-up period during which all participants performed a home exercise program. Participants exited the trial ten weeks from the day of their fracture. Measurements of hand and forearm strength were taken weekly both during the immobilisation period (Week 1 to 5) and on removal of the plaster (Week 6 to 10) post fracture. Measurements of range of motion were taken weekly on removal of the plaster (Week 6 to 10) post-fracture. An independent investigator who was blind to group allocation performed all measurements. Ethical approval for the study was given by the hospital ethics committee and participants provided informed consent.

Participants

Patients with fractures of the distal radius were eligible provided they were 18 years of age or older. They were excluded if they had open skin lesions, nerve or tendon damage associated with the fracture, or if the fracture required surgical fixation. They were also excluded if they had known pathology in their intact arm since measurement of strength and range of motion of the intact side were used as a reference against which to gauge recovery in the fractured side.

Intervention

Participants allocated to the experimental group were provided with a compression pump apparatus to use at home (Figure 1) and instructed fully in its use. The apparatus consisted of a compression pump connected to an inflatable cuff (Challis et al 2006) positioned around the proximal forearm flexor and extensor muscle bulk under the plaster. The compression pump was designed to pump air into a reservoir and, at designated periods, release a pressurised volume of air into the inflatable cuff. All components were standard electrical equipment. The apparatus operated on 240 volts and had a high-pressure safety lockout relay. The system was safety tested and complied with Australian electrical standards. One inflation/deflation of the cuff took 10 seconds and 60 compressions were applied per treatment session. The cyclic pneumatic pressure was applied twice per day (morning and evening) taking ten minutes for each session. This regime was based on the work of Rubin and Lanyon (1987) who found beneficial effects of external mechanical loading on intact turkey bones. The absolute compressive force applied to the fracture could not be pre-determined and thus an indirect method was used to devise a treatment dosage. This involved controlling the potential compression force experienced at the fracture site by pre-setting the pressurising period of the compression

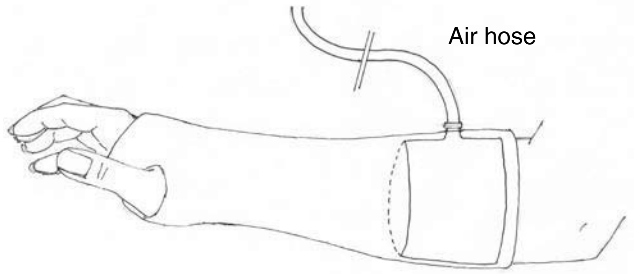

Figure 1. Diagram illustrating the position of the inflatable cuff under the plaster.

pumps reservoir to a level that was tolerated without discomfort. Testing the apparatus on two cases prior to the commencement of the study predetermined the pressurising period. A pressurising period of 3.5 seconds was found to result in a cuff inflation that did not produce any pain at the fracture site. It was considered that a pneumatic pressure on the forearm musculature that did not produce any pain at the fracture site would at best create an osteogenic effect, and at worst not interfere with the healing process. All participants in the experimental group received the same dosage of cyclic pneumatic pressure for the period they were in plaster (five weeks following the one week spent in a split cast). Participants were asked to complete a form to monitor their use of the compression pump apparatus.

The control group received usual care of immobilisation in a plaster cast and did not use the compression pump apparatus while they were in plaster.

Participants in both the experimental and control groups were asked to use the fractured arm while in the plaster to the extent that it felt comfortable and to actively make a fist 100 times each day. It was considered that this would provide a more stringent test of cyclic pneumatic soft-tissue compression than no exercise. After removal of the plaster, all participants were given a program of strengthening and stretching exercises for the hand, wrist, and forearm to be carried out twice a day for four weeks (Wakefield and McQueen 2000).

Outcome measures

In clinical practice, one of the most common forms of measurement of fracture healing is function (Kenwright et al 1991) and measuring function over time can be used as an indicator of progress (Goodship and Kenwright 1985). Function was measured as power grip strength, pinch grip strength, key grip strength, and supination strength as well as wrist flexion/extension and forearm supination/pronation range of motion. Power grip strength was measured using a Jamar dynamometer with participants in a seated position with the elbow fully extended (Mathiowetz et al 1985, Kuzala and Vargo 1991). Pinch grip and key grip strength were measured using a dynamometer in the same position. Supination strength was measured isometrically using a torquometer made and calibrated specifically for use in this trial. The total range of movement from flexion to extension and supination to pronation was measured using a goniometer.

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Table 1. Characteristics of participants who were included and those lost to follow up.

Characteristic	Included participants		Participants lost to follow up	
	Exp (n = 10)	Con (n = 9)	Exp (n = 1)	Con (n = 1)
Age *(yr)*, mean (SD)	49 (14)	60 (9)	20	26
Gender, *(M:F)*	4:6	0:9	1:0	0:1
Side of wrist fracture, *(R:L)*	3:7	2:7	0:1	0:1
Hand dominance, *(R:L)*	9:1	7:2	1:0	1:0

Exp = experimental, Con = control

Data analysis

The outcome measures of the fractured side are presented both in absolute terms and as a percentage of the intact side as an indication of the biomechanical strength of a healing fracture. The rate of change of the outcome measures was examined using mixed-design analyses of variance to investigate any interaction between group and time. Age, gender, and fractured side (left or right) were used as covariates in the analyses. The analyses were not on an intention-to-treat principle as two participants were omitted from the analyses since insufficient data were collected from them to warrant their inclusion.

Results

Flow of participants through the trial

Twenty-one patients with fractures of the distal radius were recruited over a two-year period. On average, participants were enrolled in the trial 9.4 days post fracture (range 5–14). Table 1 presents the participant characteristics. The records of fracture severities were reviewed from the case notes. Fracture severity was rated as Type 1 if it was extra-articular and undisplaced, Type 2 if it was extra-articular and displaced, Type 3 if it was intra-articular and undisplaced, and Type 4 if it was intra-articular and displaced (Rockwood and Green 1996). A chi square analysis suggested that the experimental group contained participants with more severe fractures ($p = 0.06$). Of the 21 participants who entered the trial, 11 were allocated to the experimental group and 10 to the control group. Two participants were lost to follow-up: one participant (experimental group) removed the plaster prematurely and could not receive the intervention, and the other (control group) failed to attend measurement sessions and withdrew within the first three weeks of the trial.

Compliance with trial method

Examination of the monitoring forms completed by the experimental group revealed that participants who completed the trial (n = 10), delivered the compression 93% of the time during the immobilisation period. Participants from both groups performed their exercise program 90% of the time during the post-immobilisation period.

Effect of intervention

Group data for the 10 measurement occasions are presented in Table 2 and Figure 2, while individual data for the 10 measurement occasions are presented in Table 3 (see eAddenda for Table 2 and Table 3). Group data for Week 6 and 10 measurement occasions and between-group data are presented in Table 4.

The covariates of age, gender, and fractured side (left or right) were found to have no significant influence on strength or range of motion. As a percentage of the intact side, the experimental group improved significantly faster than the control group in power grip strength ($F_{(1,18)} = 3.373$, $p = 0.001$), pinch grip strength ($F_{(1,18)} = 5.153$, $p < 0.001$), key grip strength ($F_{(1,18)} = 3.860$, $p < 0.001$), and supination strength ($F_{(1,18)} = 4.393$, $p < 0.001$). *Post hoc* contrasts showed that for all strength measures the two groups became significantly different by Week 8 post fracture. These contrasts indicate divergence occurring at Week 6 (removal of the plaster cast) and progressing through to Week 10 (end of trial period) where the two groups are observed to show significant difference in all strength measures (Table 2 and Figure 2.). In Figure 2a–d, it can be observed that, on average, the experimental group achieved by four weeks the strength that the control group achieved by six weeks post fracture. As a percentage of the intact side, the experimental group improved no faster than the control group in flexion/extension range of motion ($p = 0.11$) or supination/pronation range of motion ($p = 0.91$) during the post-immobilisation period.

By Week 6, as a percentage of the intact side, the experimental group had 12% (95% CI 7 to 17) more power grip strength, 24% (95% CI 17 to 32) more pinch grip strength, 15% (95% CI 7 to 23) more key grip strength, 26% (95% CI 15 to 37) more supination strength, 8% (95% CI 3 to 13) more flexion/extension range of motion, and 14% (95% CI 5 to 22) more supination/pronation range of motion than the control group. By Week 10, as a percentage of the intact side, the experimental group had 24% (95% CI 16 to 32) more power grip strength, 26% (95% CI 19 to 34) more pinch grip strength, 28% (95% CI 18 to 37) more key grip strength, 29% (95% CI 16 to 42) more supination strength, 15% (95% CI 8 to 21) more flexion/extension range of motion, and 10% (95% CI 2 to 18) more supination/pronation range of motion than the control group.

Discussion

Most interventions for fractures of the distal radius involve immobilising the fracture which subsequently reduces the level of mechanical stimulus. This happens at a time when the maximal rate of new bone formation is required. It has been shown that it only requires a short period of daily mechanical stimulation to enhance new bone formation in healing fractures (Goodship and Kenwright 1985, Kenwright and Goodship 1989, Kenwright et al 1991, Kenwright and Gardener 1998, Challis et al 2006). This preliminary randomised controlled trial has found a faster recovery of muscle strength as a result of a short period of daily cyclic pneumatic soft-tissue compression which mechanically stimulated distal radial fractures during the period of

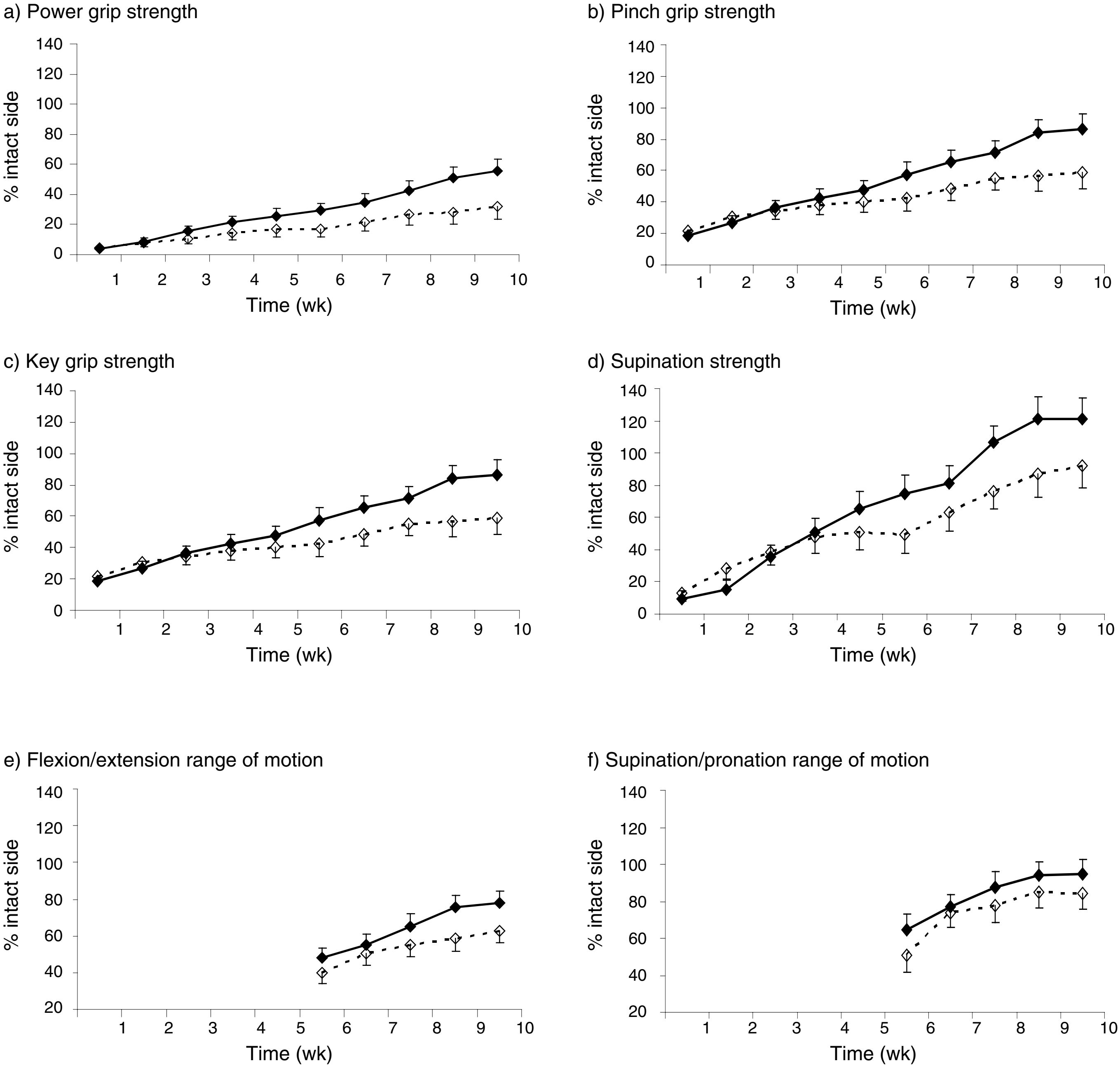

Figure 2. Mean (SD) of a) power grip strength, b) pinch grip strength, c) key grip strength, d) supination strength, e) flexion/extension range of motion, and f) supination/pronation range of motion as a percentage of the intact side for the experimental group (solid line) and control group (dotted line) from Week 1 to Week 10.

immobilisation, suggesting enhanced fracture healing.

In terms of muscle strength, a different pattern of recovery was observed between the experimental group and the control group during the immobilisation period. The experimental group consistently showed a linear rate of recovery while the control group tended to plateau between Week 4 and 6. On average, the experimental group achieved at four weeks post fracture the mean strength that the control group achieved at six weeks post fracture. This finding has strong parallels with the *in vivo* ovine study where fractures treated with cyclic pneumatic compression were not significantly different at four weeks to control fractures at six weeks in terms of mechanical, histological and radiographic features (Challis et al 2006). These parallel findings support the proposition that the measures of function used in this human study reflect fracture healing.

Although cyclic pneumatic soft-tissue compression had a beneficial effect on the rate of recovery of strength, it appeared to have no effect, compared with usual care, on the rate of recovery of range of motion following removal of the plaster. However, the amount of recovery of range of motion was larger in the experimental group. This suggests that the recovery of range of motion may be more closely related to the length of the period of immobilisation. The

Table 4. Mean (SD) of each group, and mean (95% CI) difference between groups for strength and range of motion at Week 6 and Week 10.

Outcome	Groups				Difference between groups	
	Week 6		Week 10		Week 6	Week 10
	Exp n = 10	Con n = 9	Exp n = 10	Con n = 9	Exp minus con	Exp minus con
Strength						
Power grip *(kg)*	9.0 (1.5)	3.5 (1.0)	18.3 (2.9)	7.9 (1.7)	5.8 (4.0 to 7.1)	10.4 (7.5 to 13.3)
Power grip (% intact side)	29 (5)	17 (5)	56 (8)	32 (8)	12 (7 to 17)	24 (16 to 32)
Pinch grip *(kg)*	4.5 (0.6)	2.5 (0.4)	6.3 (0.9)	3.6 (0.5)	2.0 (1.4 to 2.6)	2.68 (1.8 to 3.5)
Pinch grip (% intact side)	77 (7)	53 (8)	103 (7)	76 (8)	24 (17 to 32)	26 (19 to 34)
Key grip *(kg)*	5.1 (1.0)	2.7 (0.5)	7.3 (1.1)	4.0 (0.5)	2.5 (1.5 to 3.4)	3.3 (2.2 to 4.5)
Key grip (% intact side)	57.7 (7.9)	42.4 (8.4)	86.3 (9.7)	58.6 (10.4)	15.3 (7.4 to 23.2)	27.7 (18.0 to 37.4)
Supination *(kg)*	19.6 (4.4)	6.7 (1.4)	32.7 (8.4)	12.0 (1.1)	13.3 (8.8 to 17.7)	20.7 (12.3 to 29.2)
Supination (% intact side)	75 (11)	49 (12)	121 (13)	92 (14)	26 (15 to 37)	29 (16 to 42)
Range of motion						
Flex/ext *(deg)*	67 (5)	49 (9)	116 (14)	85 (9)	18 (12 to 23)	31 (17 to 45)
Flex/ext (% intact side)	48 (5)	40 (6)	78 (7)	63 (7)	8 (3 to 13)	15 (8 to 21)
Sup/pron *(deg)*	125 (14)	83 (16)	175 (16)	155 (16)	44 (30 to 57)	20 (4 to 36)
Sup/pron (% intact side)	65 (9)	51 (9)	95 (8)	85 (9)	14 (5 to 22)	10 (2 18)

Flex/ext = flexion/extension, Sup/pron = supination/pronation

compliance with post-immobilisation exercises for both groups was greater than 90% and both groups improved their range of motion. Loss of range of motion is often a long-term complication of fractures. The findings from this current study and our previous research using the ovine model suggest that, if compression is applied during the immobilisation period, the plaster could be removed at Week 4 to allow earlier mobilisation of the arm and minimise secondary complications such as loss of range of motion. Further research would be required to test this hypothesis.

There are limitations of the current study due to its preliminary nature. Outcomes were muscle strength and joint range of motion, which are volitional measures, rather than direct measures of bone formation. Nevertheless the preliminary findings are encouraging, suggesting that future research is warranted and providing information to enhance the design of a future clinical trial. For example, the groups were not stratified for severity of fracture in the randomisation process. There was a trend towards the presence of more severe fractures in the experimental group in this current study. This unevenness, coupled with a relatively small sample size, has meant that the confidence intervals are probably wider than they should have been. Future stratification of groups according to the severity of the fracture would eliminate this bias. On the other hand, this current study may have been a more stringent test of the effect of compression in enhancing recovery of function, given that the group containing more severe fractures improved faster.

The successful implementation of cyclic pneumatic soft-tissue compression in clinical practice in this study could see physiotherapists involved more in the management of fractures. In situations where compression was indicated, physiotherapists would be ideally suited to administer and monitor compression. If the application of compression could effect a faster removal of the plaster, then the earlier commencement of strength and range of motion exercises should further enhance recovery.

The superior gains in muscle strength and joint range of motion achieved by the experimental group in this preliminary randomised controlled trial suggest that cyclic pneumatic soft-tissue compression was successful in stimulating fractures of the distal radius mechanically. Future trials investigating pneumatic soft-tissue compression should include larger groups and stratification of the groups according to the severity of fracture. Furthermore, future trials could investigate whether the beneficial effects of the compression can be increased if (i) the mechanical stimulus is tailored to each patient, and (ii) the plaster is removed at four weeks post-fracture.

eAddenda: Tables 2 and 3 available at www.physiotherapy.asn.au compliance with post-immobilisation exercises for both groups was greater than 90% and both groups improved their range of motion. Loss of range of motion is often a long-term complication of fractures. The findings from this current study and our previous research using the ovine model suggest that, if compression is applied during the immobilisation period, the plaster could be removed at Week 4 to allow earlier mobilisation of the arm and minimise secondary complications such as loss of range of motion. Further research would be required to test this hypothesis.

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eAddenda: Tables 2 and 3 available at www.physiotherapy.asn.au

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